

REMARKS

Claims 1-41 were pending in this application. Claims 1-3, 6, 7, 9-13, 16-24, 35, and 37-41 are rejected under 35 U.S.C. § 102. Claims 4, 5, 8, 14, 15, 26-34, and 36 are rejected under 35 U.S.C. § 103. Applicants cancel claims 1-41 without disclaimer of or prejudice to the subject matter recited therein. Applicants add new claims 42-71. Support for the new claims can be found, for example, in the previously presented claims and on pages 1-2, 8-9, 25 and 34 (lines 6-10) of the as-filed specification. No new matter is added by these amendments.

I. The Claims Are Not Anticipated

A. The Examiner rejects claims 1-3, 6, 7, 9, 11-13, 17-24, 35 and 37-41 under 35 U.S.C. § 102(b) as allegedly being anticipated by Holbrook (U.S. Patent No. 5,403,741). Office Action, at page 2. The Examiner essentially asserts that Holbrook teaches the same method of culturing and/or sub-culturing a microorganism as recited in the instant application. *Id.*, at pages 2-4.

According to the M.P.E.P., to support a conclusion of anticipation “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” § 2131 (quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). In addition, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Id.* (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

Solely to advance prosecution of this application and without acquiescing in the Examiner's rejection, Applicants cancel claims 1-3, 6, 7, 9, 11-13, 17-24, 35 and 37-41 and add new claims 42-71. New independent claim 42 recites the limitation "wherein said microorganism is filamentous and said process maintains said microorganism in a genetically stable state over a prolonged period." Applicants respectfully submit that the new claims obviate the Examiner's rejection because Holbrook only describes an apparatus and methods for the selective culture of motile bacteria. Moreover, Holbrook emphasizes that the method relates to testing for motile bacteria in public health applications such as the surveillance of food hygiene, environmental hygiene and pollution, where it is desirable to shorten the culturing process. Holbrook describes the need for rapid culturing and testing of bacteria that can be achieved in less than one week. See, e.g., column 1 (lines 15-26 and 60-64) and column 2 (lines 46-49). In contrast, the instant application makes it clear that the sub-culturing process is intended for long-term storage of filamentous microorganisms (e.g., at least six months under specific conditions that maintain genetic stability). See, e.g., specification, at pages 19, 21, and 25.

In addition, Holbrook describes methods for testing for motile bacteria cultured in a single vessel that includes liquid nutrient medium suitable for resuscitation and growth of motile bacteria. See, column 2 (lines 52-55 and 66-68). In contrast, the instant claims 42 and 49 recite "a first vessel" containing solid growth supporting medium and "a second vessel" containing solid growth supporting medium. (emphasis added). Therefore, the instant process (and apparatus) is not confined to a single vessel and

does not include placing a sample into a culture vessel containing liquid medium.

Applicants respectfully assert that the claimed invention is patentably distinct from the method of culturing bacteria disclosed by Holbrook.

For the reasons above, Applicants request reconsideration and withdrawal of the rejection of claims 1-3, 6, 7, 9, 11-13, 17-24, 35 and 37-41 under 35 U.S.C. § 102(b) as anticipated by Holbrook.

B. The Examiner rejects claims 10-12 under 35 U.S.C. § 102(b) as allegedly being anticipated by Entis et al. (U.S. Patent No. 4,397,955). Office Action, at page 4.

According to the Examiner, Entis et al. discloses “a process that includes providing a growth medium in culture vessel (40); growing a population of a microorganism on or in the growth medium; and sampling the population for subculture” *Id.*

Solely to advance prosecution of this application and without acquiescing in the Examiner’s rejection, Applicants cancel claims 10-12. Accordingly, Applicants respectfully submit that the rejection of claims 10-12 is moot. Sampling processes are now covered in new claims 66-68, which all depend from claim 42. Applicants respectfully submit that the new claims obviate the Examiner’s rejection because Entis et al. describes a transfer mechanism for microorganisms and, more specifically, a device for duplicating a growth pattern of microorganisms. Entis et al. does not disclose sampling a filamentous microorganism grown in a solid growth-supporting medium as recited in instant claim 66. Nor does Entis et al. contemplate sampling by removing a cross-section of the solid growth-supporting medium through which the microorganism has grown. Lastly, Entis et al. does not describe a process for sub-culturing and

maintaining a microorganism in a genetically stable state for a prolonged period.

Therefore, Applicants respectfully submit that Entis et al. does not anticipate claims 66-68 because it fails to disclose the identical invention and does not teach each element of the instant claims.

For the reasons above, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 10-12 under 35 U.S.C. § 102(b) as anticipated by Entis et al.

C. The Examiner rejects claim 16 under 35 U.S.C. § 102(b) as allegedly being anticipated by Heefner et al. (U.S. Patent No. 5,231,007). Office Action, at page 4. According to the Examiner, Heefner et al. disclose that pharmaceutical compositions produced by microorganisms are known in the art. *Id.* The Examiner asserts that the patentability of a product does not depend on its method of production. *Id.*

Again, solely to advance prosecution of this application and without acquiescing in the Examiner's rejection, Applicants cancel claim 16. Because there is no counterpart to original claim 16 in the new claims submitted herewith, Applicants respectfully submit that the rejection of claim 16 is moot.

Applicants request reconsideration and withdrawal of the rejection of claim 16 under 35 U.S.C. § 102(b) as anticipated by Heefner et al.

II. The Claims Are Not Obvious

A. The Examiner rejects claims 4, 5, 8, 14, 26-34 and 36 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Holbrook (U.S. Patent No. 5,403,741). Office Action, at page 6. The Examiner essentially asserts that various aspects of the instant

invention, including testing a sample from the second container, maintaining sterile conditions, and determining the optimum components of the culture system, are obvious based on the alleged teachings of Holbrook. *Id.*, at pages 6-7.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all the claim elements. Furthermore, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." See M.P.E.P. § 2143.01 (quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970)). Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine reference teachings. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Third, there must be a reasonable expectation of success. See M.P.E.P. § 2143.

Solely to advance prosecution of this application and without acquiescing in the Examiner's rejection, Applicants cancel claims 4, 5, 8, 14, 26-34 and 36. New independent claim 42 recites the limitation "wherein said microorganism is filamentous and said process maintains said microorganism in a genetically stable state over a prolonged period." In contrast, Holbrook only describes an apparatus and methods for culturing motile bacteria over a short period for testing purposes. Therefore, Applicants

respectfully submit that Holbrook fails to teach or suggest all the elements of the new claims.

In addition, Applicants submit that there is no suggestion or motivation to modify the method of Holbrook to obtain the instant invention. Holbrook teaches a method of propagating motile bacteria for public health applications (e.g., testing for such microorganisms in food). If their presence is suspected, potentially contaminated samples must be cultured rapidly and tested to identify the bacteria that develop so that effective counter-measures can be put into place as quickly as possible. Therefore, Holbrook teaches that it is desirable to shorten the culturing process. See, e.g., column 2 (lines 46-49). Furthermore, Holbrook discloses that the contaminated sample is cultured in a single vessel containing liquid medium (column 2, lines 52-55 and 66-68). In contrast, the instant claims recite “a first vessel” containing solid growth supporting medium and “a second vessel” containing solid growth supporting medium. The Holbrook process and apparatus are in direct contrast to those of the instant invention, which is intended to enable maintenance of a stable population of filamentous microorganisms over a prolonged period of time (typically over many years or decades). Therefore, Holbrook teaches away from the instant invention so that one skilled in the art would find no suggestion or motivation to devise a method and apparatus for long-term maintenance of filamentous microorganisms. Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness based on the alleged teachings of Holbrook.

For the reasons above, Applicants request reconsideration and withdrawal of the rejection of claims 4, 5, 8, 14, 26-34 and 36 under 35 U.S.C. § 103(a).

B. The Examiner rejects claims 14 and 15 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Entis et al. (U.S. Patent No. 4,397,955) in view of Rudat et al. (DE 4123107). Office Action, at page 7. The Examiner asserts that "it would have been obvious to one of ordinary skill in the art to employ the system of the primary reference of Entis et al. for the transfer of the stored microorganisms as suggested by Rudat et al. so as to provide a means recognized in the art for ensuring that the entire population of microorganisms within the Petri dish are sampled for use to make a desired product in a fermentation device." *Id.*, at pages 7-8.

Again, solely to advance prosecution of this application and without acquiescing in the Examiner's rejection, Applicants cancel claims 14 and 15. Applicants add new claims 69 and 70, which are dependent on new claim 42 and recite a process for manufacturing a metabolite. According to the M.P.E.P., "[i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)). Applicants respectfully submit that instant claims 69 and 70 are allowable at least due to their dependence from allowable claim 42.

As noted above, the prior art references when combined must teach or suggest all the claim elements. The cited references do not teach or suggest sub-culturing and maintaining a filamentous microorganism in a genetically stable state over a prolonged period in solid growth supporting medium. In addition, the references do not teach, e.g.,

"permitting said microorganism to grow from the body of medium in the first vessel into the body of medium in the second vessel through said second location," as recited in claims 42 and 49. Therefore, Applicants respectfully submit that the Examiner has failed to make a *prima facie* case of obviousness.

For the reasons above, Applicants request reconsideration and withdrawal of the rejection of claims 14 and 15 under 35 U.S.C. § 103(a).

III. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claimed invention is neither anticipated nor rendered obvious by the prior art references cited by the Examiner. Applicants therefore request reconsideration and reexamination of the application, and the timely allowance of the pending claims. Should the Examiner feel that this application is not in condition for allowance, Applicants request that he contact their undersigned representative at 202-408-4072.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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